SERVED: December 14, 2001

NTSB Order No. EA-4928

UNITED STATES OF AMERICA
NATIONAL TRANSPORTATION SAFETY BOARD
WASHINGTON, D.C.

Adopted by the NATIONAL TRANSPORTATION SAFETY BOARD
at its office in Washington, D.C.
on the 13th day of December, 2001

JANE F. GARVEY, Administrator, Federal Aviation Administration, Complainant, v. FRANK BOSELA, Respondent.	Docket SE-15725

OPINION AND ORDER

The Administrator and respondent both appeal the written initial decision of Administrative Law Judge William A. Pope, II, issued on January 18, 2001, after a hearing that amassed fourteen days of testimony and numerous exhibits over four separate sessions between January and August 2000.[1] By that decision, the law judge affirmed the Administrator's emergency revocation of

[1] The law judge's 34-page initial decision is attached.

all airman certificates, including Airline Transport Pilot ("ATP") Certificate Number 0002135921, for respondent's alleged refusal to submit to a Department of Transportation ("DOT")-required random drug test in violation of Federal Aviation Regulation ("FAR") section 61.14(b).[2] We grant respondent's appeal, and deny the Administrator's appeal.

The Administrator's Amended Emergency Order of Revocation (the text of which is set forth in footnote 1 of the law judge's attached initial decision) alleged that on April 14, 1999, respondent, a captain for Airborne Express ("Airborne"), provided a urine specimen pursuant to Airborne's DOT-mandated random drug testing program. Subsequent testing of the specimen by Laboratory Corporation of America ("LabCorp") revealed that it contained an unnaturally high level of nitrite (6,909 µg/mL), indicating that the specimen had been adulterated.[3]

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[2] FAR section 61.14(b), 14 C.F.R. Part 61, states:

> **Sec. 61.14 Refusal to submit to a drug or alcohol test.**
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> (b) Refusal by the holder of any certificate or rating issued under this part to take a drug test required under the provisions of appendix I to part 121 or an alcohol test required under the provisions of appendix J to part 121 is grounds for --
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> * * * * *
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> (2) Suspension or revocation of any certificate, rating, or authorization issued under this part.

[3] Appendix I, Part 121, defines a refusal to submit to a drug test:

(continued . . .)

At the hearing, the Administrator and respondent presented extensive factual and expert testimony, and numerous documentary exhibits.[4] The Administrator, in her case in chief, presented testimony about the collection of respondent's sample from the nurse who performed the task, as well as the expert testimony of Federal Aviation Administration ("FAA") Inspector Ralph Gallegos, of the FAA's Office of Aviation Medicine, who concluded that the procedures utilized on April 14, 1999, met the requirements of 49 CFR Part 40, including those pertaining to the security and integrity of collected samples. In addition, the Administrator presented the testimony of the LabCorp individuals who performed, respectively, the qualitative and quantitative nitrite analysis of respondent's specimen. Finally, the Administrator presented the testimony of Dr. Frank Esposito, director of LabCorp, and accepted by the law judge as an expert in forensic toxicology, who testified about the qualitative ("dipstick") and quantitative ("Olympus AU800" or spectrocolorimetric) testing procedures, and

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(continued . . .)

> Refusal to submit means that an individual failed to provide a urine sample as required by 49 CFR Part 40, without a genuine inability to provide a specimen (as determined by a medical evaluation), after he or she has received notice of the requirement to be tested in accordance with this appendix, or engaged in conduct that clearly obstructed the testing process.

[4] The law judge's initial decision sets forth the hearing record in considerable detail. See Initial Decision ("I.D.") at 4-17. We summarize some, but by no means all, of that material here to provide context for our discussion, but our decision is based upon the entire record.

chain of custody practices, followed by LabCorp. Dr. Esposito testified that the nitrite testing results of respondent's specimen were reliable.

Respondent denied adulterating his specimen and testified that he did not know of any reason why the specimen tested positive for nitrite. Respondent also presented the testimony of Dr. Bruce Goldberger, accepted by the law judge as an expert in forensic toxicology, who expressed, among other things, concerns about the validation of the nitrite testing procedures utilized by LabCorp.

In rebuttal, the Administrator presented, in addition to more testimony from Dr. Esposito, testimony from Dr. David Kuntz, accepted by the law judge as an expert in forensic toxicology, and Dr. Yale Caplan, accepted by the law judge as an expert in forensic toxicology and urine adulteration testing. Drs. Kuntz and Caplan testified that the nitrite testing results from both the dipstick test and the Olympus AU800 machine were reliable.

The law judge found, after making credibility assessments against respondent’s contradictions of the nurse’s recollections about the specimen collection process, that:

> there is no credible evidence that the collection cup and specimen bottles used by [r]espondent were accidentally contaminated with nitrite at the collection site, or that the urine specimen provided by the [r]espondent was accidentally or maliciously contaminated with nitrite by someone other than [r]espondent after it left the collection site while in transit to the laboratory, or at any time while at the laboratory facility prior to the time the testing of that urine sample occurred.

I.D. at 22. The law judge also found that the dipstick nitrite test was not scientifically suitable, but that the Olympus AU800 nitrite test (which indicated 6,909 µg/mL) was scientifically suitable and, based on that test, upheld the section 61.14(b) violation. The law judge affirmed revocation.

On appeal, respondent argues, among other things, that: (1) required collection procedures were not adequately followed, (2) the nitrite testing at LabCorp was not conducted pursuant to protocols "pre-approved" by the Department of Health and Human Services ("DHHS"), (3) the Olympus AU800 nitrite testing was not sufficiently validated to demonstrate scientific reliability, and (4) the law judge's finding that the dipstick test was not scientifically suitable mandated dismissal of the action, because two separate tests were required.[5] The Administrator appeals the law judge's finding that the dipstick test was not scientifically suitable.

We adopt as our own, for purposes of this appeal, the law judge's credibility-based[6] and thoroughly-reasoned determinations regarding the integrity of the collection process and the security of respondent's sample. In terms of the ultimate issues

[5] The Board does not have jurisdiction to rule on Constitutional issues. See, e.g., Administrator v. Lloyd, 1 NTSB 1826, 1828 (1972) (Board has no authority to review constitutionality of FAA regulations).

[6] See, e.g., Administrator v. Smith, 5 NTSB 1560, 1563 (1986) (deference to credibility determinations, unless shown to be arbitrary or capricious); Chirino v. NTSB, 849 F.2d 1525 (D.C. Cir. 1988) (the Board should reverse a law judge's findings when a witness's testimony is "inherently incredible").

presented by the Administrator's and respondent's appeals, the questions we need to address are: (1) whether the then-applicable guidelines required two tests be used to demonstrate that respondent adulterated his sample with nitrites, and (2) if two tests were required, whether the law judge erred in finding that the qualitative "dipstick" test utilized by LabCorp was not scientifically suitable.

Respondent argues that nitrite adulteration testing was required to be performed using a two-test, two-aliquot process. DHHS document PD-35, which set forth then-applicable binding "guidance" on all Part 40 drug testing laboratories, requires that nitrite concentration tests "follow scientifically suitable methods and produce results which are accurately quantified." Ex. A-5. Respondent argues that it was generally understood by the scientific community that "scientifically suitable methods" meant that a two-test, two-aliquot process was necessary, and in support of this argument he points to testimony provided by both parties' experts. The Administrator, on the other hand, argues that "DHHS guidance did not call for the use of two procedures and the testing of two aliquots until July 28, 1999 [when PD-37 was issued], approximately two and one-half months after LabCorp tested respondent's specimen."

We think this record demonstrates that the then-applicable DHHS guidance did, in fact, mandate a two-test, two-aliquot approach to testing for nitrite adulteration in the context of mandatory DOT drug testing. When asked by respondent's counsel whether the two-test, two-aliquot requirement specifically

mentioned in PD-37 was, essentially, a requirement for scientific suitability, Dr. Esposito, for example, answered "yes." Tr. at 503-10. Dr. David Kuntz, who testified for the Administrator as an expert in forensic toxicology, also appears to have embraced a similar view when he testified that a "two-test system using separate aliquots and separate technology, when available" is a "constituent element" of scientific suitability as it applies to nitrite testing. Tr. at 2276-77. Dr. Goldberger also emphasized the importance of the two-test, two-aliquot approach, calling it "the premise for good forensic laboratory practices."[7] Tr. at 1858-59. Indeed, we think the specificity of PD-37 can be seen not as a new requirement, but, rather, a more precise enunciation of what many of the experts who testified already understood: a two-test, two-aliquot approach is necessary to ensure a scientifically suitable test that can be relied upon to yield valid, accurate results.

Turning to the Administrator's appeal of the law judge's finding that the qualitative "dipstick" test performed by LabCorp on respondent's sample was not scientifically suitable, we discern no error in the law judge's determinations and

[7] Even Dr. Caplan, whom the law judge cited in support of his determination that PD-35 only required one test, cautioned that his testimony that a single test might be adequate to prove that respondent adulterated his urine sample was from a "purely scientific point of view" and admitted that in the context of forensic toxicology a two-test approach was the better practice. Dr. Caplan also testified that in the context of validity testing, he had recommended the two-test approach "from a forensic point of view."

conclusions. The law judge, after noting that LabCorp did not produce any written validation study about the suitability of using the Bayer-manufactured diagnostic dipsticks in a manner contrary to the manufacturer's instructions and for a purpose other than for which they were engineered, found that the qualitative "dipstick" test "was not validated in any meaningful way that could be reviewed." I.D. at 24-27. Based on this lack of written validation, as well as conflicting expert testimony about whether the qualitative "dipstick" test procedures, as explained by Dr. Esposito, were reliable, the law judge concluded that the "dipstick" test was not scientifically suitable.

The Administrator argues, essentially, that the law judge ignored the opinions of Drs. Esposito, Kuntz and Caplan that the qualitative "dipstick" test was appropriately validated by Dr. Esposito, and, instead, favored the contrary and less-qualified opinions of Dr. Goldberger, who, although qualified as an expert in forensic toxicology, was not qualified as an expert in the field of urine adulteration. Respondent, on the other hand, argues that despite Bayer's warning that its dipstick instructions "MUST BE FOLLOWED EXACTLY TO ACHIEVE RELIABLE RESULTS," the qualitative nitrite adulteration test designed by LabCorp's Dr. Esposito deviated from those instructions and, significantly, was not properly validated in accordance with DHHS guidance.

These factors persuade us that the law judge did not abuse his discretion when he found that LabCorp's qualitative "dipstick" test was not sufficiently validated and, therefore,

was not demonstrated to be scientifically suitable. Although we do not necessarily doubt the scientific explanations rendered by the Administrator's experts as to why LabCorp's deviations from Bayer's instructions were valid, we are troubled somewhat by the lack of any written validation study, or written results from a thorough and formal validation study, in this record. Indeed, although the Administrator's witnesses who listened to Dr. Esposito's testimony generally found his description of the validation experimentation he performed more than two years prior to be descriptive of a reasonable or "excellent" validation, Dr. Esposito, working from memory, incorrectly testified that he believed he only deviated from one of Bayer's instructions when, in fact, he deviated from three of them. Tr. at 967-968. Without a written validation study, or at least contemporaneous scientific notes describing it, we are now unable to reliably evaluate the validity of the qualitative procedure given the uncertainty surrounding the thoroughness of Dr. Esposito's recollections. Moreover, unlike validation documentation created contemporaneously with the development of this procedure, we now must view Dr. Esposito's recollections in the context in which he made them -- in the face of a challenge to the accuracy of the results obtained by a procedure he designed. We discern no error in the law judge's resolution of this matter.

ACCORDINGLY, IT IS ORDERED THAT:

1. The Administrator's appeal is denied;
2. Respondent's appeal is granted;
3. The law judge's initial decision is reversed to the

extent it is inconsistent with this opinion and order; and

4. The Administrator’s Amended Order of Revocation is reversed.

HAMMERSCHMIDT, GOGLIA, and BLACK, Members of the Board, concurred in the above opinion and order. CARMODY, Vice Chairman, did not concur. BLAKEY, Chairman, did not participate.